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CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that the annexed is a true copy of the Provisional Specification as filed on 3 September 1997 with an application for Letters Patent number 328668 made by Safer Sleep Ltd.

Dated 05 October 1998.

Neville Harris
Commissioner of Patents

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Patents Form No. 4 Our Ref: PT501903

Patents Act 1953

PROVISIONAL SPECIFICATION

ANAESTHESIA APPARATUS

We, **SAFER SLEEP LIMITED**, a New Zealand company, of 32 Glendowie Road, Glendowie, Auckland New Zealand do hereby declare this invention to be described in the following statement:

BC:PT0467154

This invention relates to methods and apparatus for storage, dispensing and use of administrable substances, particularly anaesthetics.

Whilst the invention is primarily directed to anaesthetics, the invention is not limited thereto and may be used in other related cases.

In the past, methods and apparatus for storage and use of administrable substances such anaesthetic drugs and the like, have, in the main, relied upon the skill, alertness and self-imposed systems of practitioners.

It has long been recognised that errors can and do occur, sometimes with disastrous consequences, particularly in the area of anaesthesia where on occasions, owing to tiredness, distraction, adverse conditions (e.g. emergencies) or lack of attention to procedures which have become routine, errors can be made which can result in extremely serious consequences including patient death.

A likelihood of errors is also exacerbated by an increasing complexity of drug administration procedures, types of drugs and their subsets, together with often potentially confusing markings, packagings, concentrations and the like which all but the most alert practitioner might otherwise mistake, especially in emergency or other stressful circumstances.

The flow-on effect is that in some countries practitioners, and organisations such as the hospitals with whom they work often have difficulty in obtaining at reasonable levels an appropriate degree of negligence or malpractice cover, or the costs of dealing with an accident can astronomical. Further, there is a trend toward the use of criminal law, (e.g. manslaughter prosecutions) in cases of drug administration error.

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It is an object of this invention to come some way in reducing, the likelihood of errors in substance administration, to at least come some way in overcoming the abovementioned problems or at least provide the public with a useful choice.

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Other objects of this invention will become apparent from the following description.

According to one aspect of this invention there is provided a method of monitoring substance administration including the steps of: prior to use, forming a support device having a predetermined substance site for a preloaded predetermined substance carrier; forming a second predetermined site for such predetermined substance carrier; taking said predetermined substance carrier from said first site for use and after use, positioning said carrier in the second site to monitor said use.

According to a further aspect of this invention the monitoring of method includes the step of applying a colour code at least to portions

of said first site and second site, together with at least a portion of said predetermined substance carrier in way in which a predetermined code relationship can be verified between said first and second sites and said carrier.

According to a still further aspect of this invention, the method includes the step of monitoring by a sensing means the presence or absence of the carrier in said first and/or second site.

According to a further aspect of this invention, method includes the step of comparing a sequence of presence or absence of said carrier in said first and/or second sites against predetermined sequences.

According to a still further aspect of this invention the method includes the step of comparing presence or absence of said carrier in said first and/or second sites with a predetermined sequence and including the step of providing a warning when presence and/or absence out of the predetermined sequence occurs.

According to a still further aspect of this invention there is provided apparatus for storage and use of administrable substance carriers including a body portion defining of a plurality of sites in relation to which predetermined carriers can be positioned, said sites provided in pairs, a first site and a second site, said first site adapted to receive a predetermined preloaded substance carrier and said second

site adapted to receive a discharged or used carrier, identification means provided for verification of said carrier relative to said site.

According to a still further aspect of this invention there is provided a package of contained administrable substances intended to be administered in a predetermined manner, said package including a plurality of predetermined first sites and second sites, at least one of said first sites charged with a preloaded carrier for said administrable substance and means provided between said carrier and said first site for verifying presence or absence of said carrier on said site, said second site adapted for receiving a used carrier after initial removal from said first site.

Other aspects of this invention will become apparent from the following description. Modifications are envisaged and may be incorporated without departing from the scope or spirit of the invention.

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One form of the invention will now be described with reference to a preferred embodiment and the accompanying drawings in which:

Figure 1 is a perspective view of an anaesthetic trolley showing the apparatus of the invention mounted therewith.

Figure 2 is an alternative embodiment of the tray according to the invention.

Figure 3 is an alternative embodiment of the tray according to the invention.

Whilst the invention is described with reference to anaesthesia processes and anaesthetic products and the drawings, the invention is not limited thereto. The invention is applicable in other areas of practice where monitoring of use and a normally predetermined sequence of use is desired.

It is relatively common for many anaesthesia practices to be carried out according to relatively standard and repeatable steps, although naturally there often are variations. In other words, there is a sequence through which the practitioner normally passes during the course of an operation. For example, the anaesthetist would normally administer drugs or medications in volumes and concentrations dependent on, amongst other things, body mass, degree of anaesthesia required, age, blood pressure etc., however, the drugs used in the main generally tend to follow certain predetermined sets of procedures.

In the past, there has been propensity for the practitioner to rely on a combination of skill, experience, memory, colleague verification and verification in relation to notes, to ensure the correct drugs are used.

The present invention provides a means of reducing reliance on the above procedures to reduce mistakes. In

particular, the invention provides a basis for reliance upon sequencing, monitoring and verification, utilising such features as colour coding, bar codes and similar techniques to achieve risk reduction.

Many aspects of anaesthesia have highly engineered safety systems, for example, gas bottle pin index systems to prevent the administration of a wrong gas from an anaesthetic machine. Further, gas mixture control systems in place make the administration of a hypoxic gas mixture virtually impossible. These engineering advances operate in conjunction with procedural approaches designed to enhance safety and are backed up by monitors such as in line oxygen monitors and pulse oximeters. In contrast, the administration of intravenous drugs has not changed substantially this century, although the number, range and complexity of drugs has undergone an exponential increase.

With reference to Figure 1 typically drug ampoules are stored in the drawer D of an anaesthetist's trolley T. There is usually no uniformity of presentation, either visually or spacially and traditionally anaesthetists draw up contents of the ampoules into syringes S for administration of the drugs in many steps, all of which are highly error prone.

The present invention provides both a means and apparatus to minimise errors utilising in the preferred form of the

invention prefilled colour coded carriers in the form of syringes S. Preferably the syringes S will be prefilled by the hospital pharmacy or pharmaceutical manufacturer/supplier and be neatly colour coded by class of drug and other details which may be necessary. Preferably the colours indicate drug classes rather individual drugs as a drug error between classes is usually much more dangerous than one within a class.

It will be appreciated that the mass production of prefilled syringes and the like is substantially less prone to error than traditional techniques of staff filling to present demand requirements.

Colour coding by class will also minimising the total colours used making the classification system simpler. Whilst colour coding is preferred for classes of drugs, in alternative arrangements it will also be appreciated that a combination of drug class/individual drug may also be provided, for example utilising a two-tier code system or some other identifier.

Particularly with reference to Figure 2, in the preferred form coloured syringe labels S1 are used incorporating the name of the drug in bold print of a size that they will wrap around the syringe barrel in a way that the colour code can be seen from any likely syringe orientation. In other forms of the invention its is envisaged the syringe body or plunger itself can be colour coded, such as at manufacture.

It is envisaged syringe marking scales will be retained and further, different densities or shades of colour on the label may used to indicate the strength of the drug.

In alternative arrangements it is envisaged that syringes or other dispensing apparatus may be prefilled and supplied by drug companies in a substantially complete state. By providing the drugs in a "batch manufactured" manner it is envisaged that further risk reduction will be achieved.

In the preferred form of the invention syringes S are provided in conjunction with a drug tray 1. It is envisaged that anaesthetic procedures will be divided into preferably three classes according to factors, such as complexity, for example "minor", "intermediate" and "major".

In the preferred form, preferably sealed sterile plastic trays 1 will be prepackaged with prefilled colour coded syringes S of the drug classes needed in the "standard" anaesthetic procedure for each of the three classes, resulting in three classes of drug tray 1.

The tray 1 design preferably incorporates separate sites or compartments 2 each, if required, incorporating individually sealed rip-top covers 3 for each compartment 2. Each compartment 2 is the same coded colour 2c as the prefilled syringe S which that compartment 2 is intended to house either

by a suitable label or permanent marking 2c on the compartments. The compartments 2 are preferably arranged in a positionally sensitive manner allowing the syringes S to be used from, for example, left to right across the tray 1 as the anaesthetic proceeds.

Each compartment 2 is preferably provided with two subcompartments, a first subcompartment 2a or site, and a second subcompartment 2b or site. The first subcompartment 2a is preferably provided adjacent to a tray front 4 for preloaded, filled syringes S and is designated the "ready" subcompartment 2a. The other, preferably rearward second subcompartments 2b is provided for used or empty syringes S (not shown) and is designated the "used" subcompartment 2b.

In addition to compartments 2a prepacked with filled syringes S, drug trays 1 in each class will also preferably provide also initially empty compartments 2 (including both empty first and second subcompartments). These empty compartments 2 are provided for use with drugs which are frequently but not always used and are therefore considered not strictly "standard". It is envisaged that the additional compartments 2 can, for example, be supplied with prefilled syringes S from a standard drug drawer D in the anaesthetists trolley T before starting the anaesthetic procedure.

It is envisaged that colour coding systems and/or labelling will also be used in relation to the additional components 2 by inserting, adhering or otherwise positionally placing both on the syringe S and the additional compartment 2 appropriate colour codes or other identifier means.

Once a syringe S has been used, if further doses are required these can be obtained by reloading the relevant "ready" subcompartment 2a of the tray 1 with additional prefilled syringes S from a source, perhaps a colour coded drug drawer D elsewhere in the anaesthetists trolley, sympathetically or correspondingly set out and possibly similarly or otherwise coded for ready verification. Used syringes S will accumulate in the relevant "used" subcompartment 2b of the tray 1 as the anaesthetic proceeds, thus providing ready verification of the identity and amount of drug used.

It is envisaged that there will always be a certain number of drugs which are not readily available in prefilled syringes S. In most instances, it is envisaged that these drugs will be infrequently used, or are perhaps drugs which are not stable in a plastic syringe S for long periods. A section of the tray 1, for example a righthand section 5 thereof is designed to accommodate the drugs only available in ampoules.

In the preferred form of the invention, colour coded compartments 2 in this section comprise three

subcompartments, a forwardmost compartment 2c for the placement of ampoule a from a colour coded ampoule drawer (not shown) elsewhere in the drug trolley, the middle subcompartment 2e for placement of the syringe S conventionally filled from the ampoule a and colour coded; together with a rearmost compartment 2c for an empty ampoule a (not shown) after the syringe S has been filled.

It will be appreciated that in such a system, keeping track of syringes S and ampoules a in this way maintains a visually striking monitor of drug administration and at any time it is possible for practitioners to check at a glance what has been administered and, equally important, what has not been, to reduce the potential for error to the individual anaesthetist and also to assist where one anaesthetist hands over to another during long anaesthetics.

Whilst the invention has been described with reference to a series of "standard" combinations of anaesthetics, it is to be appreciated that alternative arrangements can also provide for the use of, for example, an emergency tray of a generally similar specification to the standard anaesthetics tray 1 prepackaged with prefilled colour codes syringes S of drugs used in an anaesthetic emergency.

An emergency drug tray of this type may have the greatest potential to reduce drug error since it is during an

emergency that errors are most likely to occur. The emergency tray 1 may be stocked or restocked from an emergency "reserve" drug drawer D in a similar way to the standard trays 1.

The invention envisaged that additional monitoring checking and notification systems are incorporated into the apparatus. It is envisaged in the preferred form of the invention that each syringe S will incorporate some identification means to positively identify the contained drug, either by class, individual drug, concentration or all. Preferably such an arrangement is incorporated into a conveniently arranged bar code positioned on the syringe S, however in alternative forms of the invention, other identification means may be provided, for example electronically stored identification apparatus, magnetic or digital devices and the like.

In this arrangement, as each syringe S is taken from the ready compartment 2a, it may be, for example, "swiped" under a conveniently positioned reader as part of the drug administration routine, whereupon a calm computer generated voice will announce the name and dose of the drug just swiped. The computerised announcement will preferably occur at a time anticipated to be before the actual drug administration. It is envisaged that this will considerably reduce the risk of drug error by supplementing the anaesthetist's already received information with further auditory information to hopefully allow correction of any errors before administration.

In the preferred form of the invention, information received by the reader or a sensor will be conveyed and stored as a record, for example in a microprocessor based device. It is anticipated that the practitioner may, on receiving confirmation of the identity of syringe S from the computerised announcement or verification may physically confirm, for example by depressing a "confirm" key, to confirm verification and/or administration, by taking such action either prior to or subsequent to administration of the identified drug. In this way, it will be appreciated that both physical confirmation and verification may be provided, and further, the apparatus will provide a record of the actions of the practitioner. It is envisaged that such a record may be valuable subsequently, should complications arise, or other checking be considered appropriate.

It is also envisaged that the monitoring procedure may incorporate a series "standard" or "specific" administrations previously worked out for the anaesthetic procedure. In such circumstances, it is envisaged that the monitoring apparatus will sense and then compare the removal of syringes S from the "ready" subcompartment 2a of the tray 1 against a predetermined "standard administration order" and not only will provide auditory verification of the syringe S taken, but may also provide an auditory or other warning to the anaesthetist of any variants from the predetermined routine of administration.

Whilst the invention has been described with reference to syringes S and trays 1 with an associated bar code reader, it is envisaged that in alternative forms of the invention the compartments 2 can be provided with suitable sensing means 6, for example positioned in the base 7 of each subcompartment 2a/2b. Further, the syringes S can be provided with detection means thereon in the form of magnetic/digital devices and others, which can be readily sensed by the sensors 6 placed within the base of the tray 1.

It is envisaged that the sensors may be set up to distinguish individual syringes and even drug classes and characteristics in the compartments 2 for passing to monitoring and recording apparatus such that at any stage an accurate and reliable verification of supply, use and countback of drugs/ syringes used can be provided and also be monitored against predetermined and anticipated usage as a cross-checking procedure.

Whilst the invention has been described with reference to the provision of sensors 6 placed within the base of the tray 1, in alternative embodiments of the invention, it is envisaged that the upper portion of the trolley, or some other support apparatus adapted to be used with the tray 1 of this invention may be provided with suitable sensor means, and the tray being provided of a means substantially inert to interaction between the syringe identification means and the sensor means so as

enable simple formation of the trays, or provision of the trays as a liner for separate support apparatus. In this way, it will be appreciated that the cost of tray 1 can be kept to a minimum and further, the sensing apparatus will not interfere unduly with necessary sterilisation and other hygiene steps inevitably required.

Whilst the invention has been described with reference to a tray 1 and to prefilled syringes S, the invention is not limited to such arrangements and it is envisaged that other drug administration apparatus can be provided and utilised in conjunction with the methods and apparatus described.

In the preferred form of the invention, preferably the tray 1 apparatus is provided as a plastics or metal tray 1 able to be sterilised and adapted for ready placement and holding of the syringes S in the required layout for substantially standardised use and providing the first "ready" and the second "used" subcompartments 2a and 2b in a visually separate manner.

In the further embodiment of the invention as described with reference to Figure 3, preferably the drug tray 1 is vacuum formed in a thin plastics material, for example a transparent or translucent plastics sheet which is capable of being readily cleansed by heat, irradiation and the like. The tray 1 is preferably arranged in a generally "tapered" configuration so as to be "stackable" with similar trays 1, such that a "pack" of trays 1

can be supplied for general use. Preferably the tray 1 is dimensioned for use with a standard drugs trolley T, substantially as shown in Figure 2 and further the outer peripheral dimensions of the tray 1 are such that preferably a pair of trays 1 according to Figure 3 can be mounted side-by-side on the standard drugs trolley T as is typically used in a theatre or other hospital situation.

In this form of the invention preferably the sites or compartments 2 in this form of the invention are positioned on either side of an enlargement 10 upon which a plurality of arcuate rests or syringe sites 11 are provided. The syringe sites 11 are in this form inclined toward a front 4 of the tray 1 such that syringes S can be readily supported, and viewable by the user. The syringe S after use is able to be positioned in the second compartment 2b which has tapered apertures provided in the second compartment 2b into which a boss B of the syringe S body can frictionally engage, thus mounting the syringe S in a readily visible and verifiable substantially upright manner after use.

The syringe sites 11 preferably include a predetermined array (preferably three in respect to each compartment 2 "set") of arcuate rests into which the syringe S can be mounted, inclined forwardly to the user to provide good vision for the user and the syringe S and coding (for example colour coding at 12 on the sites 11, and on the body of the syringe S).

It will be appreciated that colour coded and possibly prefilled syringes S or dedicated syringes S for particular drugs can be readily positioned on the relevant sites 11 on the rests and on the tray 1 in a verifiable positional relationship.

The second compartments 2b, preferably incorporate the dimpled apertures 14 so shaped to readily frictionally engage the boss B in the apertures 14 to support the syringe S in a substantially upright position.

Preferably a frontal or supplementary tray 15 is provided across the front 4 of the tray 1 for incidental items and the like as may be required during the course of the anaesthesia operation.

It is envisaged that the enlargement 10 created by the raised area defining the syringe sites 11 will readily enable the enclosed mounting of the sensing apparatus described hereinbefore.

It is also envisaged that the drugs trolley T can be arranged on it's upper portion thereof with an enlargement over which the tray 4 can fit. In this assembly a colour coding or identification apparatus 12 can be positioned either on the trolley T prior to the application of a tray 1 thereover, where the colour coding or identification indicia 12

can be "read" through clear or translucent portions of the tray 1, or alternatively, the colour coding or indicia 12 can be affixed on an underside of the tray 1.

Preferably additional identification means may be provided substantially corresponding on a front face 16 of the enlargement 10 which enables additional simple verification of the colour code relevant to the particular "row" of the compartments, the syringe sites 11 and in the second compartment 2b.

Where the invention incorporates the use of a "standard" drugs tray 1 incorporating a series of "standard" combinations of anaesthetics, it is to be appreciated that the drugs and drugs tray 1 may be stocked in a "kit" form, where a recess provided beneath the enlargement 10 is used for storage of the drugs, syringes S and other items to be used in an anaesthesia operation, optionally contained within a tear-off sheet plastics sheet and the like mounted across adjacent portions of an underside of the tray 1, thus enclosing the items on the underside of the tray 1.

It will be appreciated that this alternative embodiment provides a relatively simply constructed means to enable a user to monitor of drug types positioned on the tray to verify drug administration at any time during the operation.

The stackable nature of the tray in the alternative embodiment enables a convenient "bulk" store of trays 1 to be held (for example in packs of 10, 20 and the like) for convenient usage when required.

It is envisaged that tray 1 packs may well incorporate sets of separate self-adhesive labels with colour or other "indicia" coding for mounting on the tray 1, on syringes S and vials V for matching purposes. The sets of colour codings may be arranged for either substantially "standard" use codes or alternatively, for special or specific colour codes to be provided in special use arrangements.

It is generally envisaged that the colour codes are arranged according to drug class, however this is not essential to the invention.

In the alternative form of the invention coded labels arranged for the syringes S are provided in a substantially inverted L shaped configuration, to enable positioning along the syringe body and provision of a readily verifiable code together with a bar code (or interactive indicator for a sensor arrangement) yet still leaving a visual "window" to enable use of syringe volume graduations thereon.

Thus, by this invention there is provided a method and apparatus for administration of substances which substantially

reduces the risk of errors and provides significant convenience and security.

SAFER SLEEP LIMITED
BY THEIR ATTORNEYS
BALDWIN SON and CAREY

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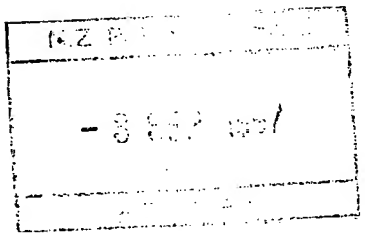

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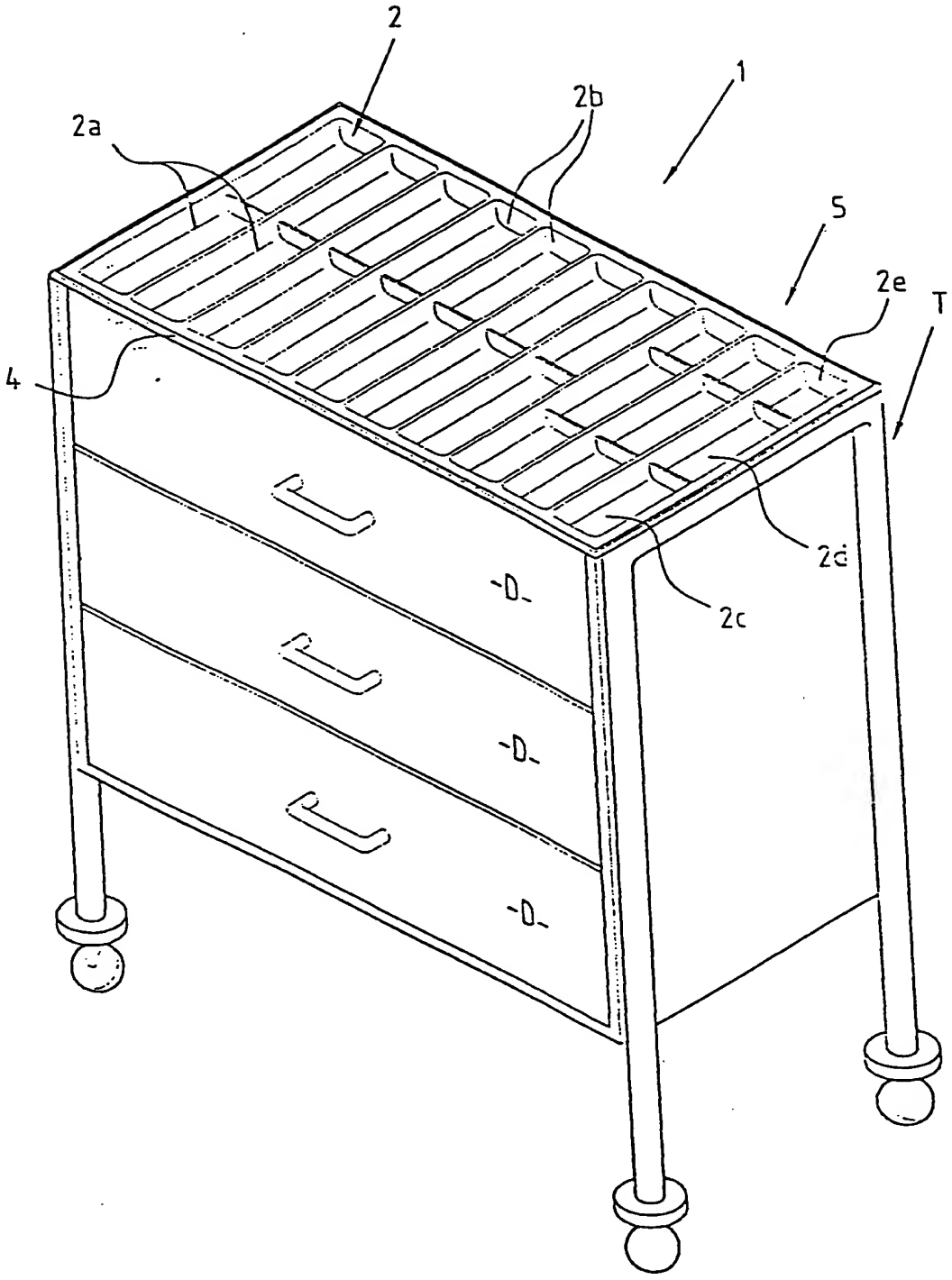

FIG.1.

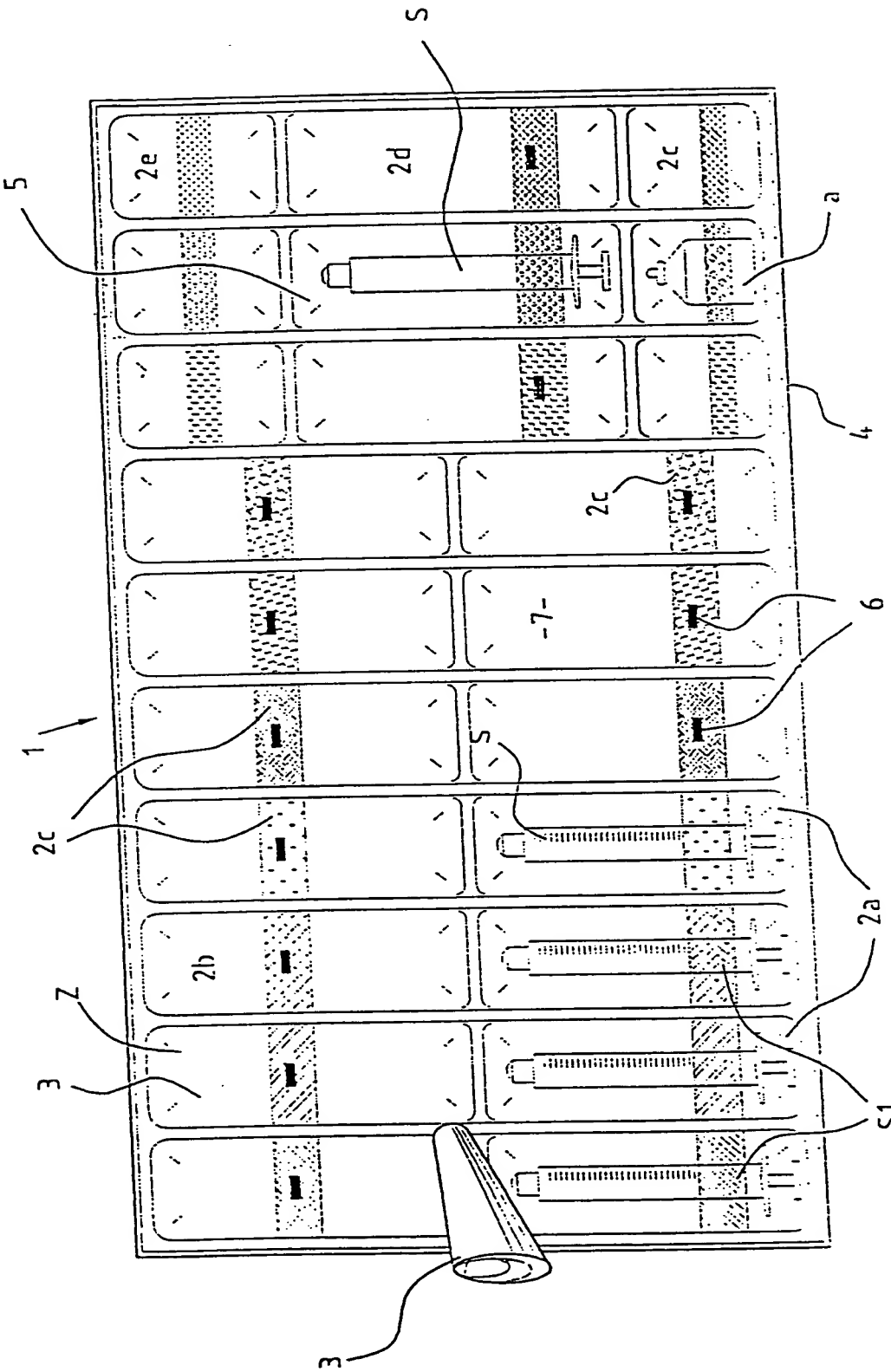

FIG.2.

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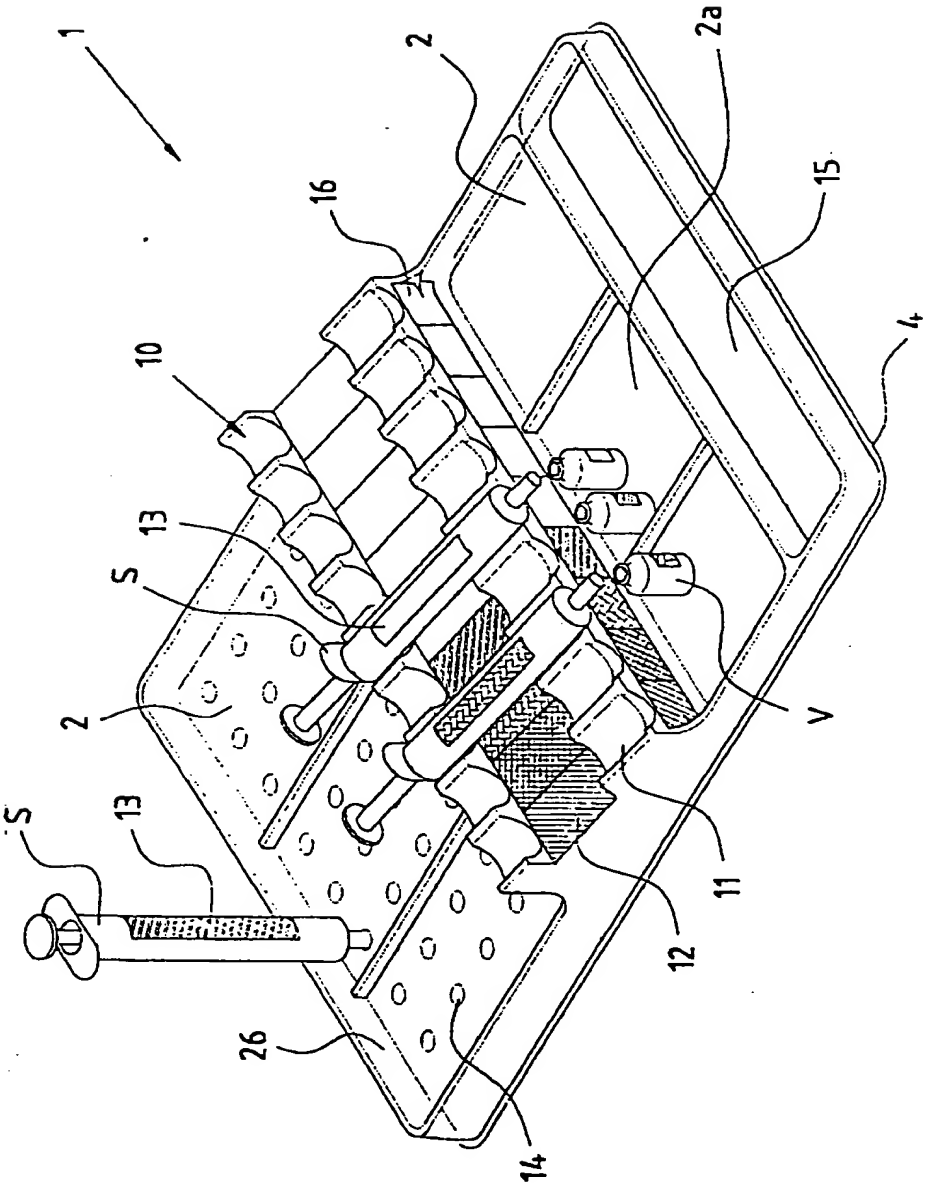

FIG.3.